

### **REMARKS**

Reconsideration of the application is respectfully requested. Claims 58, 60, 62-71, 89, 91-94, and 96-125 are pending. Applicant respectfully notes that the Examiner's statement that the prior obviousness rejections are maintained "[i]n light of no amendments to the claims" (*see* Office Action at p. 4) is incorrect because claims 58, 89, 92-93, 96, 98, 103, and 105 were in fact amended in the previous Response filed February 3, 2009.

### **Examiner Interview**

Examiners Kendra D. Carter and Sreeni Padmanabhan are thanked for all courtesies extended to the inventor, Samuel P. Sawan, and his counsel, Lydia Olson and Dianna Goldenson, during the telephonic Examiner interview conducted on September 9, 2009.

During the interview, the inventor explained that the claimed invention was developed in an effort to provide a contact biocide – e.g., a biocide that physically and chemically bonds to the skin and remains on the skin surface such that a microorganism must contact the skin surface in order for the biocide to be transferred to the microorganism. When the microorganism contacts the biocide film on the skin surface, the microorganism's membrane is compromised thereby killing the microorganism. This mechanism of action is facilitated by coulombic interactions between the biocide and the microorganism – e.g., cationic polymers of the claimed biocide attract anionic charges on bacterial membranes. As described by the inventor, because the biocide is bonded to the skin, any moisture (e.g., water) that contacts the film-covered skin surface remains free of biocide in antimicrobially effective amounts. The inventor further added that the claimed invention is a breakthrough in technology because prior biocides did not provide "persistent antimicrobial activity" that can withstand exposure to moisture (i.e., "forming a moisture-resistant film"), as called for in the pending claims. *See also* Specification at p. 13, lines 6-9 ("The term 'persistence' as used herein refers to the ability of an antimicrobial material to inhibit bacterial regrowth on skin for an extended period of time after the initial antiseptic action caused by application of the antimicrobial formulation.").

Additionally, the patentability of the claimed invention over the combination of Smith (U.S. Patent No. 5,576,006) and Fox (U.S. Patent No. 5,374,432) was discussed during the interview. In

particular, Smith was distinguished from the claimed invention by the inventor and his counsel because Smith discloses a slow release antimicrobial product that gradually elutes bioactive components from a surface into solution, whereas the claimed invention provides a moisture-resistant film that maintains persistent antimicrobial activity on a surface and does not elute antimicrobially effective amounts of bioactive components into solution. In support of this explanation, the inventor and his counsel directed the Examiners' attention to the claim term "substantially water-insoluble" and its corresponding definition in the specification at page 15, lines 4-8, which states:

As used herein, "substantially water-insoluble" means that bioactive components in the disinfecting compositions do not dissolve, elute, leach or otherwise provide species into a liquid environment in contact with the compositions at levels that would result in solution disinfection, that is, in antimicrobially effective amounts.

The inventor and his counsel further argued that even if one of ordinary skill in the art combined Fox's silver compound with Smith's antimicrobial complex of a biguanide polymer and quaternary ammonium or amine, the resulting composition would still not be substantially water-insoluble, as called for in the claimed invention.

The above-described arguments are reiterated in further detail below.

### **Obviousness Rejections**

Claims 58, 60, 62-64, 8-71, 89, 92, 93, 96, 98-103, 105, 106, 108-114, and 117-124 have been rejected under 35 U.S.C. §103(a) as obvious over Morlet (WO 97/00076) in view of Fox (U.S. Patent No. 5,374,432) and further in view of Smith (U.S. Patent No. 5,576,006). The Examiner cites Morlet as disclosing a topical antimicrobial composition containing poly(hexamethylene biguanide) (PHMB), but admits that Morlet does not teach either a composition containing an antimicrobial metallic material or the formation of a moisture-resistant film. The Examiner cites Fox as disclosing a topical antimicrobial composition containing silver and an antibiotic, but admits that Fox does not teach the formation of a moisture-resistant film. The Examiner cites Smith as disclosing antimicrobial complexes containing biguanide compounds, such as PHMB, that are less water soluble and more hypoallergenic, thus providing a longer lasting effect without having to use the antimicrobial agent in higher dosages. According to the Examiner, Smith teaches a complex that

forms a moisture-resistant film. From this, the Examiner concludes that it would have been obvious to combine a biguanide polymer with an antimicrobial metallic material in a moisture-resistant film applied to the skin in order to provide improved antimicrobial activity that is longer lasting and more hypoallergenic.

The rejection is traversed, and reconsideration is respectfully requested.

The pending claims are not obvious because, *inter alia*: (i) none of the cited references discloses a “substantially water-insoluble” antimicrobial component that provides “a persistent antimicrobial activity,” as called for in the pending claims; and (ii) combining Fox’s silver compound with Smith’s antimicrobial complex of a biguanide polymer and antimicrobial agent would not yield a composition that is “substantially water-insoluble,” as called for in the pending claims.

First, the Examiner admits that neither Morlet nor Fox discloses a composition that forms a moisture-resistant film. *See* Office Action at p. 9. Hence, these references fail to teach a substantially water-insoluble antimicrobial component. Smith does not cure the deficiencies of Morlet and Fox because the antimicrobial complex disclosed in Smith likewise fails to qualify as being “substantially water-insoluble,” as this claim term is defined in the present specification. *See* p. 15, lines 4-8.

Smith relates to complexes formed between polycarboxylic acids and functional biocides, which have a higher combined molecular weight that renders these complexes “more water insoluble” due to their increased size (col. 2, lines 45-54; col. 3, lines 17-19). Smith does not state that its complexes are water-insoluble or even substantially water-insoluble. In fact, Smith’s antimicrobial complexes are specifically designed to be slightly water-soluble so that the biocide can be released into solution. This is described in Smith as follows (col. 3, lines 19-124):

The formation of these simple but larger complexes or compounds has the effect of creating a slower release type of functional compound. Therefore, a larger lasting effect is achieved with these complexes without having to use the microbial or other type of biocidal agent or herbicide in higher doses or frequent doses.

Thus, Smith expressly states that its complexes release biocide (the functional compound). The mere fact that Smith states that these complexes have the “effect” of slow release, does not mean that the biocide could be retained on the surface in an alternative embodiment. Such an

interpretation would directly contradict the entire remaining context of this reference, which clearly describes antimicrobial complexes designed to release biocide into solution. Smith even points out disadvantages that occur when biocidal contact is too prolonged (or too brief), stating that (col. 1, lines 28-31):

The problems found with using many antibacterial or antifungal agents are that such agents are irritating after prolonged contact or are quickly absorbed by stockings because they are water soluble.

Accordingly, Smith distinguishes its compositions from formulations that remain on a surface for an extended period of time. Moreover, Smith would have discouraged one of ordinary skill from preparing a moisture-resistant film that provides such persistent antimicrobial activity on the skin because doing so would have been thought to cause skin irritation. Along these same lines, Smith would also have discouraged the preparation of compositions such as those disclosed in Morlet and Fox, which are water soluble and would likely be absorbed by footwear, such as stockings, too rapidly to be sufficiently effective. Hence, one of ordinary skill in the art reading Smith, Morlet, and Fox would have had no reason to create an antimicrobial product that would purposefully maintain antimicrobially effective amounts of biocide on the surface of the skin for a prolonged period of time, and would not have had any basis for reasonably predicting a successful result in doing so. On the contrary, based on Smith's teachings, one would have expected a negative result – skin irritation.

Moreover, even the Smith complexes that are slowest to dissolve nevertheless fail to qualify as being "substantially water-insoluble" because these complexes are likewise designed to provide an antimicrobial effect by releasing biocide into solution. Furthermore, beyond the significant solubility difference between the Smith complexes and the claimed antimicrobial components, there is a significant structural difference as well. That is, in the claimed invention, microorganisms are attracted to the claimed antimicrobial component due to coulombic interactions between the cationic biguanide polymer (which has a positive charge) and the microorganisms (which have membranes carrying an overall negative, anionic charge). These attractive forces are absent from Smith, which uses a cationic polymer to form a salt with a carboxylate anion (*see* col. 4, lines 37-45). Salts are electrically neutral and thus would not attract the anionic charge on microorganism membranes.

This helps explain why it is important for the Smith biocide to be released into solution in order to increase the level of contact between biocide and microorganisms – i.e., if the biocide remained on the surface without attracting microorganisms, one would expect it to be highly ineffective. This structural difference also helps to explain why Smith does not (and even discourages) formation of a moisture-resistant film comprising a substantially water-insoluble antimicrobial component that imparts a persistent antimicrobial activity on the skin.

Second, combining Fox's silver compound with Smith's antimicrobial complex of a biguanide polymer and antimicrobial agent would not yield a composition that is substantially water-insoluble, as called for in the pending claims, because it is well known by those of ordinary skill in the art that combining a slightly soluble compound (e.g., silver) with a slightly soluble complex (e.g., biguanide polymer complexed with quaternary ammonium or amine) would yield a slightly soluble composition, not a "substantially water-insoluble" composition. In other words, those of ordinary skill would be aware of the fundamental principles of solubility, including this additive property, and would therefore reasonably expect two slightly soluble compounds to remain slightly soluble even when combined. Consequently, the claimed "substantially water-insoluble" antimicrobial component is not a predictable result of the combination of Fox's silver compound with Smith's antimicrobial complex. *See* MPEP §2143.01(III) ("The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art." (emphasis in original)).

For at least the foregoing reasons, the pending claims are not obvious over any combination of Morlet, Fox, and Smith. Therefore, Applicant respectfully requests that this rejection be withdrawn.

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Claims 65-67, 91, 94, 104, 107, 115, 116, and 125 have been rejected under 35 U.S.C. §103(a) as obvious over Morlet in view of Fox and Smith and further in view of Sawan (WO 95/17152). The Examiner cites Sawan as disclosing an antimicrobial coating solution containing the elected species of methylene-bi(N,N-diglycidylaniline) and silver iodide.

The rejection is traversed, and reconsideration is respectfully requested.

Sawan fails to cure the deficiencies of Morlet, Fox, and Smith discussed above. In particular, Sawan likewise does not teach a "substantially water-insoluble" antimicrobial component that provides "a persistent antimicrobial activity" on the skin. Thus, claims 65-67, 91, 94, 104, 107, 115, 116, and 125 are not obvious over any combination of the cited references for at least the same reasons set forth above; and Applicant respectfully requests that this rejection be withdrawn.

### **Obviousness-Type Double Patenting**

Claims 58, 60, 62-71, 89, 91-94, and 96-125 have been rejected by the Examiner under the judicially created doctrine of obviousness-type double-patenting as being allegedly unpatentable over the claims in commonly owned U.S. Patent Nos. 6,180,584; 6,030,632; 5,869,072; and 5,817,325. Upon indication of allowable subject matter in the present application, the allowable subject matter not being patentably distinct from the claims of one or more of the above-cited patents, an appropriate terminal disclaimer will be timely filed.

### **Conclusion**

In view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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